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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants,	:	
v.	:	Civil Action No. 3:11-CV-00760-JAP-TJB
HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	:	

HANMI'S OPENING *MARKMAN* SUBMISSION

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Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively "Hanmi") respectfully submit this brief in support of Hanmi's proposed claim constructions.

I. INTRODUCTION

Many terms of the patents-in-suit – U.S. Patents 5,714,504 ("the '504 patent," D.I. 86-2) and 5,877,192 ("the '192 patent," D.I. 111-9) – were construed by the Court in *AstraZeneca AB v. Dr. Reddy's Labs., Ltd.*, 05-cv-05553-JAP-TJB ("*AZ v. DRL*") (D.I. 246), reported at 2010 U.S. Dist. LEXIS 48844 (D.N.J. 2010). Many of the Court's prior constructions have been agreed to and mutually adopted by the parties here. *See* Joint Claim Construction and Prehearing Statement (D.I. 92) at pp. 1-3. Other terms of the two patents were given plain meaning by the Court in *AZ v. DRL*. The terms in Section III below are disputed.[1]

Some unusual issues are raised by virtue of the fact that, although the '192 patent purports to be a continuation-in-part ("CIP") of the '504 patent, the two have largely different disclosures, compounded by the '192 patent's confusing attempt to incorporate by reference some portions of the parent application – which contains definitions of certain terms which conflict with definitions in the '192 CIP. In several instances, Hanmi relies on actual definitions of key claim terms that are expressly set forth in the respective specifications.

II. RELEVANT CLAIM CONSTRUCTION PRINCIPLES

A. Specification Definitions Of Claim Terms Control

Where, as in several instances discussed below, the patentee provides an express definition of a claim term in the specification, that definition controls in claim construction. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051 (Fed. Cir. 2010) ("In such cases, the inventor's lexicography governs.") (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed.

[1] As reflected in Ex. 4, since the filing of the Joint Statement the parties have resolved several additional claim construction disputes.

Cir. 2005) (*en banc*)); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls."). The specification of the patent "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe the claimed invention in full, clear, concise and exact terms. *Phillips,* 415 F.3d at 1316. However, "[t]he written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." *Id.* at 1312.

B. Limitations From The Specification Should Not Be Read Into Claims

Courts cannot alter what the patentee has chosen to claim as his invention, limitations appearing in the specification should not be read into claims, and interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999); *Intervet Am., Inc. v. Kee-Vet Labs., Inc.,* 887 F.2d 1050, 1053 (Fed. Cir. 1989); *see Miken Composites, LLC v. Wilson Sporting Goods Co.,* 515 F.3d 1331, 1337 (Fed. Cir. 2008) (explaining that the patentee, responsible for drafting and prosecuting the patent, can prevent undesired results through clear drafting).

III. CLAIM TERMS IN DISPUTE AND HANMI'S PROPOSED CONSTRUCTIONS

A. The '504 Patent

1. "alkaline salt"

Each of independent claims 1, 6 and 7 recite an alkaline salt of (-)-omeprazole. Hanmi submits that this term should be construed as follows:

"Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt."

(D.I. 92-1, page 8.) The term "alkaline salts" is not defined in independent claims 1, 6 or 7. The specification, however, is clear as to its meaning and *defines* the term as the Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts, and no others. The special definition given to "alkaline salts" by AstraZeneca governs the construction of the term. *Phillips*, 415 F.3d at 1315-16 ("The specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.'") (quoting *Vitronics*, 90 F.3d at 1582).

The '504 patent clearly and consistently states that the compounds of the invention are the five inorganic salts and one organic genus of salts of an enantiomer of omeprazole. For example, the Abstract on the cover page states that "[t]he novel optically pure compounds Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of [the enantiomers of omeprazole]" as well as processes for the making and using them, and certain intermediates, are the subject matter of the '504 patent. (D.I. 86-2.) Thus, the scope of the patent is limited from the start. *See* Declaration of Jerry L. Atwood, Ph.D. ("Atwood Decl.") ¶¶ 9-10.[2]

Similarly, the "Detailed Description of the Invention" portion of the specification *expressly defines* salt scope as follows:

> ***The present invention refers to the new Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of the single enantiomers of omeprazole***, where R is an alkyl with 1-4 carbon atoms, i.e. Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole and (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, where R is an alkyl with 1-4 carbon atoms."

(D.I. 86-2, col. 2, lines 42-49 (emphasis added).) Because AstraZeneca defined the six named salt species as **the present invention**, and not as mere embodiments of it, the claims should be

[2] The credentials of a person of ordinary skill in the art in the mid 1990's concerning salt scope and optical purity issues in the '504 and '192 claims are set forth in paragraphs 7-8 of the Atwood Declaration.

construed – and limited – according to this language. Atwood Decl., ¶ 11; *see C.R. Bard, Inc. v. United States Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004) ("Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term.").

The specification further identifies the Na^+, Ca^{2+} and Mg^{2+} salts as "[p]articularly preferred" salts, and the Na^+ and Mg^{2+} salts of omeprazole (according to compounds Ia and Ib) as the "[m]ost preferred salts according to the invention." (D.I. 86-2, col. 2, line 50 – col. 3, line 15.) Beyond the most preferred Na^+ and Mg^{2+} salts, the '504 patent states that the alkaline salts are limited to the six species disclosed: "alkaline salts of the single enantiomers of the invention are, as mentioned above, beside the sodium salts (compounds Ia and Ib) and the magnesium salts (compounds IIa and IIb) exemplified by their salts with Li^+, K^+, Ca^{2+} and $N^+(R)_4$, where R is an alkyl with 1-4 C-atoms." (D.I. 86-2, col. 5, lines 7-11.) Because none of these other salts (Li^+, K^+, Ca^{2+} and $N^+(R)_4$) were actually "exemplified" in the sense of having been prepared and disclosed in column 5, AstraZeneca again clearly delineated alkaline salt scope as the six species – two that were made and four that were not. Therefore, the term "alkaline salt" of claims 1, 6 and 7 of the '504 patent should be properly construed as the Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salt species. Because the only disclosure of alkaline salts in the '504 patent specification is with express reference to the six named salt species, *and only those species*, those six species fully define the scope of "alkaline salts." *See* Atwood Decl., ¶ 12.

The prosecution history of the '504 patent confirms the construction of "alkaline salt" is limited to the Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts. The '504 patent was filed as U.S. Application Serial No. 08/376,512 ("the '512 application") on January 23, 1995 as a continuation-in-part of U.S. Application Serial No. 08/256,174 ("the '174 application"), filed as PCT/SE94/00509, dated May 27, 1994. (D.I. 86-2 cover page; D.I. 111 (certified copy of '504 patent file history),'512 Application at HAN0039510.) There were 34 claims in the '512

application as originally filed. (*Id.*, '512 application at HAN0039543-49.) Consistent with the scope of the original specification filed on January 23, 1995, most of the original claims of the '512 application were directed to the six particular salt compounds of omeprazole's enantiomers.[3] Original claim 1 of the '512 application is representative:

> 1. An optically pure enantiomeric compound comprising a Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole or (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole, wherein R is an alkyl with 1-4 carbon atoms.

(D.I. 111 at HAN0039543.) None of claims 1-34 of the '512 application as originally filed generically claimed an "alkaline salt" of (-)-omeprazole; instead, all original claims to the enantiomers were directed to only these six salt species, or a subset of them (*e.g.*, claim 30). (D.I. 111 at HAN0039543-49.) Thus, one of ordinary skill in the art would not have given broad play to the claim term "alkaline salt." Atwood Decl., ¶ 13.

On August 12, 1996, claim 1 and other original enantiomer claims were rejected based on prior art and for obviousness-type double patenting based on the parent application, No. 08/256,174, which was pending at that time. (D.I. 111, August 12, 1996 Office Action at HAN0039578-80.) In a January 21, 1997, Examiner interview summary record, the Examiner suggested that not all alkaline salt forms of S-omeprazole would be encompassed within the scope of the claims, stating: "A pharmaceutical formulation for oral administration of pure solid state (-) enantiomer of omeprazole Na-salt may be allowable *after reviewing the data in affidavit form. . . . The scope of the claim will depend on the data submitted.*" (D.I. 111, Interview Summary at HAN0039582 (emphasis added).)

In a February 12, 1997 Amendment, AstraZeneca cancelled all of original claims 1-34 and added new claims 35-44, which later issued as claims 1-10 of the '504 patent. These new

[3] Claims to a heterocyclic intermediate and processes of preparing particular compounds were also present, but are not relevant to salt scope.

claims introduced the term "alkaline salt" for the first time, in contrast to the original claims discussed above which were limited to the six salts. (D.I. 111-2, February 12, 1997 Amendment at HAN0039757-70.) AstraZeneca did not point to any support in the specification for claiming a broad genus of alkaline salts as opposed to the six salts defined as "the present invention." (*Id.*)

When it filed the February 12, 1997 Amendment, AstraZeneca also submitted a Declaration of Dr. Andersson. The Andersson Declaration reported on two clinical studies involving both the sodium salt and the magnesium salt of (-)-omeprazole. Based on the clinical data reported, AstraZeneca argued for patentability, in that the results were specifically attributed to the sodium and magnesium salts used in the clinical studies. (D.I. 111-2, Andersson Declaration at HAN0039773-94.) The Examiner allowed the pending claims on April 25, 1997. (D.I. 111-2, Notice of Allowance at HAN0039795-96.)

AstraZeneca's acquiescence in the Examiner's statement that "[t]*he scope of the claim will depend on the data submitted,*" supports a claim scope that is limited to the named species (based on "*the data submitted*" by the applicants), and is consistent with a straightforward reading of the specification. *TorPharm Inc. v. Ranbaxy Pharms., Inc*., 336 F.3d 1322, 1330 (Fed. Cir. 2003) ("[A]scertaining the scope of an issued patent, the public is entitled to equate an inventor's acquiescence to the examiner's narrow view of patentable subject matter with abandonment of the rest. Such acquiescence may be found where the patentee narrows his or her claims by amendment, or lets stand an examiner's restrictive interpretation of a claim."); *Inverness Medical Switzerland GmbH v. Princeton Biomeditech Corp*., 309 F.3d 1365, 1372 (Fed. Cir. 2002) ("A broader definition may be disclaimed, for example, where the examiner adopts a narrow definition and the applicant does not object.").

Thus, the prosecution history as a whole confirms a claim scope that is no broader than the named species in the specification as originally filed. Atwood Decl., ¶¶ 13-17.

The doctrine of claim differentiation may create a presumption that subject matter in a dependent claim should not limit the scope of the independent claim from which it depends. *Phillips*, 415 F.3d at 1314-15 ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim"). But that presumption is rebuttable, and "different terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading . . . is proper." *Hologic, Inc. v. Senorx, Inc.*, 639 F.3d 1329, 1337 (Fed. Cir. Feb. 24, 2011) (citing *Nystrom v. TREX Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005)). Here, it is of no moment that the term "alkaline salts" of Claim 1 is broader on its face than the six salt species recited in dependent claims 3 and 10. The intrinsic evidence demands a construction of "alkaline salts" that is coextant with the six named salt species – just like the scope of the *original* claims before AstraZeneca sought to broaden the salt scope in prosecution without a showing of support in the specification. Atwood Decl., ¶ 18.

Both the specification and prosecution history of the '504 patent demand a construction of "alkaline salt" as the Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts. The specification ***defines*** the "*present invention [as referring] to the new* Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} *and* $N^+(R)_4$ *salts,*" not all alkaline salts or "basic" salts as AstraZeneca now urges. During prosecution, AstraZeneca argued for the patent based data related only to the sodium and magnesium salts of (-)-omeprazole – not all alkaline or "basic" salts. By describing the preparation of only sodium and magnesium salts in the Examples, and in view of its prosecution arguments, AstraZeneca confirmed that the correct interpretation of alkaline salts is no broader than the six salt species. AstraZeneca's clear definitions and arguments rebut any presumption that the scope of the claims reciting "alkaline salt" is no different from the scope of any dependent claims reciting the

six salt species. *See ERBE Elektromedizin GMBH v. Canady Tech.*, 629 F.3d 1278 (Fed. Cir. 2010).[4]

Plaintiffs' proposed construction of alkaline salt as a "basic salt (here, a salt in which (-)-omeprazole is negatively charged) that is suitable for use in a pharmaceutical formulation" is unsupported and should be rejected for several reasons. First, "suitable for use in a pharmaceutical formulation" does not relate to the scope of salts. None of the evidence alleged by Plaintiffs as "supporting" its construction has anything to do with a definition of alkaline salt that artificially incorporates a requirement of suitability. Neither the specification nor the prosecution history hints at such a definition. Atwood Decl., ¶ 19.

Second, there is no intrinsic support for alkaline salt being defined as any "basic salt." The intrinsic evidence refers to six salt species, and only to those species. Atwood Decl., ¶ 20.

Finally, AstraZeneca has previously taken the position that "alkaline salt" in the '504 patent claims means "a compound of positively- and negatively- charged ions (cations and anions) formed under basic conditions." *AZ v. DRL.*, Civil Action No. 3:05-cv-05553 (JAP)(TAB) (D.N.J.) (D.I. 188, p. 6). AstraZeneca's shifting positions – now abandoning its previous proposed construction that required alkaline salts to be formed under a particular set of conditions, and added a functional limitation directed to suitability for use – undermine AstraZeneca's current contentions.

2. "(-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole"

[4] In *ERBE*, for example, the Court interpreted the term "low flow rate" in independent claim 35 as meaning "flow rate less than 1 liter per minute" in light of the fact that the inventors distinguished their low flow rate from a prior art reference during prosecution in order to obtain the patent, and that the specification provided an exemplary flow rate of about less than 1 liter per minute. The Court rejected the patentee's argument that such a narrow construction would render the claims surplusage. Thus, the presumption of claim differentiation was effectively rebutted by the intrinsic record. *ERBE*, 629 F.3d at 1282-83, 1286-87.

Each of independent claims 1, 6 and 7 of the '504 patent expressly recites a salt of the "(-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole." Hanmi submits that the quoted term should be construed as follows:

> "(-)-omeprazole" or the "(-)-enantiomer of omeprazole" ["(-)-omeprazole" is also known as "(S)-omeprazole"].

(D.I. 92-1, page 11.) This section addresses AstraZeneca's contentions seeking to have specific optical purity limitations included as part of the construction. It also addresses the claim term "optically pure" in claim 2 because they are intertwined – see Section III-A-3 below.

In *AZ v. DRL*, the Court noted that:

> The claims at issue expressly require the alkaline salts of the (-)-enantiomer of omeprazole. '504 patent, col. 14, lines 6-10. By focusing a person skilled in the art on the enantiomer, Astra asserts that the claims obviously require some level of optical purity. Indeed, a person of ordinary skill in the art would know that "[t]he '(-)' denotes that the compound has some level of optical purity." *Abraxis Biosciences Inc. v. Navinta*, 640 F. Supp. 2d 553, 567 (D.N.J. 2009); *see also Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 348 F. Supp. 2d 713, 725-26, 729 (N.D.W.Va. 2004) (quotation omitted).

2010 U.S. Dist. LEXIS 48844 at *18-19. The Court's recognition of the well known '(-)' symbol in the compound's name as denoting one of the enantiomers, as opposed to the racemate or the other enantiomer, comports with Hanmi's proposed construction – "(-)-omeprazole or the (-)-enantiomer of omeprazole." Atwood Decl., ¶¶ 27-28.

The Court went on to construe compounds of independent claims 1, 6 and 7 as having "high optical purity" of "at least 94% enantiomeric excess" (e.e.), basically agreeing with AstraZeneca's position (*see* 2010 U.S. Dist. LEXIS 48844 at *19-21). The Court then considered the term "optically pure" in dependent claim 2, and also adopted AstraZeneca's position: "essentially free of the (+)-enantiomer of omeprazole" and "at least 98% enantiomeric excess (e.e.)" (*see id.* at *21-23).

Hanmi respectfully asks that the Court reconsider its constructions of these terms where Hanmi was not present. When critically analyzed, the intrinsic record cannot support adding

numerical limitations to any of the '504 claims (or the '192 claims, as discussed below), despite AstraZeneca's prior arguments which persuaded the Court and influenced the ultimate constructions, but where Hanmi was not present.

The '504 patent *expressly defines* two levels of optical purity — "optically pure" and "very high optical purity:"

> With the expression "***optically pure*** Na^+ salts of omeprazole" ***is meant*** the (+)-enantiomer of omeprazole Na-salt essentially free of the (-)-enantiomer of omeprazole Na-salt and the (-)-enantiomer essentially free of the (+)-enantiomer, respectively.
>
> * * *
>
> Because it is possible to purify optically impure or partially pure salts of the enantiomers of omeprazole by crystallization, they can be obtained in ***very high optical purity, namely*** ≥99.8% enantiomeric excess (e.e.) even from an optically contaminated preparation.

(Col. 3, lines 31-36 and 43-48) (emphasis added).)

The specification makes clear that the term "optically pure" means "the (-)-enantiomer essentially free of the (+)-enantiomer." It also makes clear that "very high optical purity" means ≥99.8% e.e. AstraZeneca chose to limit the highest level of optical purity numerically and, while the '504 specification *disclosed* certain Examples as preferred embodiments, no *claim* of the '504 patent recites or requires "very high optical purity." Atwood Decl., ¶¶ 29-31.

On the other hand, AstraZeneca could have, but did not, limit the definition of "optically pure" in the '504 claims numerically.[5] Instead, the '504 patent's express definition at col. 3, lines 31-36 *avoided* any numerical lower limit. Thus, the *working Examples* in the '504 patent had to have formed the basis for AstraZeneca's prior arguments seeking a construction with a numerical limitation. But, read in context, the Examples beginning in column 6 are merely *illustrative* — as the term "Example" itself means — and no sound basis exists for including any

[5] And, AstraZeneca certainly knew how to claim optical purity numerically when it wanted to. *See* U.S. Patent 6,875,872 (Ex. 2), which has the same specification as the '504 patent.

e.e. % reported in any Example as a lower limit of optical purity in the claims. The '504 specification prefaces the Examples with the following unambiguous statement:

> The invention is ***illustrated*** by the following ***examples*** using ***preferred procedures*** for the preparation of optically pure sodium salts and magnesium salts.

(D.I. 86-2, '504 patent, col. 6, lines 26-28 (emphasis added).) While Examples of 98% e.e. are reported, a conclusion that "optically pure" in claim 2 *requires* a minimum of 98% e.e. would be contrary to the express definition in the specification ("essentially free of," col. 3, lines 31-36) as well as the suggestion at 6:26-28 that "non-preferred" procedures could yield lower optical purity values, and still be within the scope of the claims. Atwood Decl., ¶¶ 32-33.

Where, as here, the patentee provides an express definition of a claim term in the specification, that definition controls in claim construction. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051 (Fed. Cir. 2010) ("In such cases, the inventor's lexicography governs.") (quoting *Phillips*, 415 F.3d at 1316); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls."); *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed. Cir. 2007) ("When a patentee defines a claim term, the patentee's definition governs even if it is contrary to the conventional meaning of the term."). *See also Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) ("Because the inquiry into the meaning of claim terms is an objective one, a patentee who notifies the public that claim terms are to be limited beyond their ordinary meaning to one of skill in the art will be bound by that notification, even where it may have been unintended.").[6]

[6] Even though it does here, "[t]he specification need not reveal such a definition explicitly." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d at 1051-52; *see also AstraZeneca AB v. Mutual Pharm. Co., Inc.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004) ("AstraZeneca seems to suggest that lexicography requires a statement in the form 'I define _____ to mean _____,' but such rigid formalism is not required.").

In *Martek*, for example, the patentee explicitly defined the term "animal," stating that the term "means any organism belonging to the kingdom Animalia." 579 F.3d at 1380. The Federal Circuit thus simply stated "[t]hat definition controls." *Id.* Accordingly, the Federal Circuit ruled that, "because it is undisputed that humans are members of the kingdom Animalia, it was error for the district court to limit the claim term "animal" to exclude humans." *Id.* (footnote omitted). *See also 3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003) ("Because 3M expressly acted as its own lexicographer by providing a definition of embossed in the specification, the definition in the specification controls the meaning of embossed, regardless of any potential conflict with the term's ordinary meaning as reflected in technical dictionaries."); *Serrano v. Telular Corp.*, 111 F.3d 1578, 1582 (Fed. Cir. 1997) ("The inventor's definition and explanation of the meaning of the word "determining," as evidenced by the specification, controls the interpretation of that claim term."); *Novartis AG v. Mylan Pharms., Inc.*, 2011 U.S. Dist. LEXIS 99130, *13-*14 (D.N.J. Aug. 17, 2011) ("In this case, the term "enteric coating," is expressly defined in each of the patent specifications . . . . Accordingly, that definition – Novartis's proposed construction – controls.").

Accordingly, the term "optically pure" in claim 2 should be accorded its express definition in column 3 – "the (-)-enantiomer essentially free of the (+)-enantiomer." AstraZeneca cannot change the definition years later. One of ordinary skill in the art would have understood that the term "optically pure" in claim 2 would be given its *express definition* in column 3, lines 31-36. Nothing in the prosecution history is at odds with Hanmi's position. Thus, the intrinsic evidence does not support limiting claim 2 to 98% e.e. '504 patent at col. 3, lines 31-36; Atwood Decl., ¶¶ 27-33.

If dependent claim 2 is not limited numerically, certainly no basis exists for AstraZeneca to have urged in the prior case, or now, that independent claims 1, 6 and 7 of the '504 patent should demand any specific lower limit of optical purity. Yet, in *AZ v. DRL,* the Court accepted

AstraZeneca's position that Example 12 provided a basis for a minimum optical purity of 94% e.e. However, the working Examples cannot limit claim scope for the reasons set forth above. Moreover, even if they could, Example 12 provides no support for the subject matter of claims 1, 6 and 7. Those claims are directed to alkaline *salts* of (-)-omeprazole, whereas Example 12 forms the free base or neutral (*i.e.*, non-salt) form of (-)-omeprazole. Indeed, Example 12 merely illustrates the final stage of what is characterized as a novel *process* of making the enantiomers.[7] Clearly, the enantiomers of omeprazole in non-salt or neutral form are not part of the invention of the '504 patent, because they were admittedly known in the prior art.[8] Thus, Example 12 is not related to the subject matter of the asserted claims of the '504 patent. Atwood Decl., ¶ 34.

The words of a claim are generally given their ordinary and customary meaning, *i.e.*, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13. Here, the '(-)' symbol in claims 1, 6 and 7 denotes the (-)-enantiomer of omeprazole. Atwood Decl., ¶ 28. No "94% e.e." minimum should be part of the construction, nor should a "98% e.e." minimum be part of the construction of "optically pure" in claim 2. To do so would contravene a basic principle of claim construction -- limitations from the specification should not be read into the claims.

The *Phillips* court expressly warned against the "danger of reading limitations from the specification into the claim." 415 F.3d at 1323; *see also Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 908 (Fed. Cir. 2005). Yet, this was AstraZeneca's exact position in the *DRL* case, as reiterated today – ***numerical values found only in preferred embodiments***

[7] "The present invention in a further aspect provides a novel method for preparing the novel compounds of the invention in large scale. This novel method can also be used in large scale to obtain single enantiomers of omeprazole in neutral form." '504 patent, col. 2, lines 11-15. That process is claimed in AstraZeneca's U.S. Patent 5,693,818 (*see* Ex. 1 at HAN0038816), which issued from the '504 patent's parent application 256,174.

[8] "The separation of the enantiomers of omeprazole in analytical scale is described in e.g. J. Chromatography, 532 (1990), 305-19 and in a preparative scale in DE 4035455." '504 patent, col. 1, lines 27-29 (D.I. 86-2).

should be read into the claims. This approach is fundamentally contrary to unambiguous Federal Circuit precedent. "[I]nterpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.'" *Burke*, 183 F.3d at 1340 (quoting *E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988)).

Here, nothing in the '504 patent's specification declares or signifies to a person of ordinary skill in the art that any salt compound must have a minimum of 94% e.e. In fact, that value is merely the reported result for *one example* – an example of a free base, non-salt compound not related to the subject matter of the asserted claims of the '504 patent. Nothing in Example 12 lays down a ground rule that all compounds in the patent have a minimum of 94% e.e. Atwood Decl., ¶ 35. Any intent to redefine the meaning of a particular claim term away from its ordinary meaning must be clearly and unambiguously expressed in the specification. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005). "In short, a court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999).

The '504 specification unambiguously rejects AstraZeneca's contentions. It is clear that AstraZeneca's constructions requiring numerical optical purity limitations seek to *improperly import* characteristics from preferred embodiments of the working Examples into the claims. This is at odds with clear precedent. *See Playtex Prods.*, 400 F.3d at 908 ("Claims of a patent may only be limited to a preferred embodiment by the express declaration of the patentee."). No such "express declaration" is in the present intrinsic record. Atwood Decl., ¶ 35.

In sum, the compound in claims 1, 6 and 7 is simply a salt of (-)-omeprazole, and claim 2 signifies a higher level of optical purity – essentially free of the (+)-enantiomer, based on the

express definition at 3:31-36. The only term defined as having a specific, numeric lower limit is "very high optical purity," which is not claimed in the '504 patent. Atwood Decl., ¶ 36.

The '504 patent's prosecution history provides further support for Hanmi's optical purity constructions. As noted above, the '512 application as filed contained 34 claims. All of the original claims called for "optically pure" enantiomers, and none recited a specific numerical lower limit of optical purity. Original claim 1 is again shown for convenience:

> 1. An optically pure enantiomeric compound comprising a Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, wherein R is an alkyl with 1-4 carbon atoms.

(D.I. 111, at HAN0039543-49.) Following the August 12, 1996 rejection of claims, AstraZeneca responded February 12, 1997 by cancelling all then-pending claims (1-34) and adding new claims 35-44 (now issued as claims 1-10 of the '504 patent) (D.I. 111-2, February 12, 1997 Amendment at HAN0039757-70). In the new claim set, independent claims 1, 6 and 7 were broader than any original claim to the enantiomers in that they did not characterize the compounds as "optically pure." The term "optically pure" only appeared in dependent claim 36, which became claim 2 of the '504 patent. Thus, while "optically pure" in claim 2 should be construed in accordance with the patent's express definition at column 3, lines 31-36, by dropping that term from the original independent claims, AstraZeneca signaled that claims other than claim 2 encompass some measure of optical impurity. Nothing in the remainder of the prosecution history supports AstraZeneca's position that claims 1, 6 and 7 are limited to 94% e.e. and that claim 2 should be limited to 98% e.e. Atwood Decl., ¶¶ 37-38; *see Andersen Corp. v. Fiber Composites*, LLC, 474 F.3d 1361, 1369-70 (Fed. Cir. 2007) (citations omitted).

3. "optically pure"

Claim 2 recites an "optically pure" alkaline salt. Hanmi submits that this term should be construed as follows:

"essentially free of (+)-omeprazole alkaline salt, *i.e.,* the single enantiomer."

(D.I. 92-1, page 14.) For the reasons set forth in Section III-A-2 above, the express definition of "optically pure" in the '504 patent's specification at col. 3, lines 31-36, should control. The key aspect of the definition is "essentially free of," but without a numerical component. *See* Atwood Decl. ¶¶ 27-39.

4. "administration of…", "administration to…" and "a mammal including man in need of treatment"

Each of '504 patent claims 6 and 7 are method claims requiring oral *administration* of a therapeutically effective amount of the claimed pharmaceutical formulation. Claim 6 is directed to a method of inhibiting gastric acid secretion, while claim 7 is directed to a method for treatment of a gastroinflammatory disease and specifies administration "to a mammal including man in need of treatment."

The "administration" terminology in each of claims 6 and 7 should be construed as follows:

> "the prescription by a physician or other licensed healthcare professional, dispensing and ingestion."

(D.I. 92-1, page 16 and 18-19.) The phrase "a mammal including man in need of treatment" in claim 7 should be construed as follows:

> "A mammal including man in whom the need for treatment of gastrointestinal inflammatory disease is recognized and/or appreciated by the physician or other licensed healthcare professional."

(D.I. 92-1, page 20.) Hanmi's proposed constructions for the "administration" language in claims 6 and 7, as well as the "mammal in need of treatment" terminology in the method of claim 7, is clearly supported by the context of those claims, the intrinsic evidence, and the Declaration of Robert Hardi, M.D. ("Hardi Decl.").

Claim 6 of the '504 patent reads as follows:

> A ***method of inhibiting gastric acid secretion*** comprising the oral ***administration of a pharmaceutical formulation comprising a therapeutically effective amount*** of a pure solid state alkaline salt of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and a pharmaceutically acceptable carrier.

Claim 7 of the '504 patent reads as follows.

> A ***method for the treatment of gastrointestinal inflammatory disease*** comprising the oral ***administration to a mammal including man in need of such treatment*** of a pharmaceutical formulation comprising a ***therapeutically effective amount*** of a pure solid state alkaline salt of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and a pharmaceutically acceptable carrier.

(D.I. 86-2, col. 4, lines 21-34.) The meaning of "administration of" in claim 6 and "administration to" in claim 7, in the context of those claims from the standpoint of one of ordinary skill in the art in the mid-1990's, is in agreement with Hanmi's proposed construction: "the prescription by a physician or other licensed healthcare professional, dispensing and ingestion." Given the precise context of these claims in light of the manner in which such methods are actually carried out in day-to-day practice, Hanmi's interpretation is consistent with the views of a person of ordinary skill in the art in the mid-1990's. Hardi Decl., ¶¶ 20-29.[9]

AstraZeneca's Nexium® product is a pharmaceutical formulation within the scope of claims 6 and 7 (and also claims 1 and 2 of the '192 patent) and is the only commercially available product meeting that description. In the United States, Nexium® is available only by prescription.[10] (D.I. 112, Nexium Drug Package insert; purple pill.com; Hardi Decl., ¶ 23).

The context of the claim language in which the "administration" term appears makes clear that the involvement of a physician or other licensed healthcare professional ("physician") is

[9] The credentials of a person of ordinary skill in the art in the mid 1990's concerning the medical treatment aspects in the '504 and '192 claims is set forth in paragraphs 16-19 of the Hardi Declaration.

[10] Likewise, the accused Hanmi esomeprazole strontium formulation, if approved, will be available only by prescription.

required. This is because the claims require administration of a ***therapeutically effective amount*** of the pharmaceutical formulation and because in practice Nexium® is available only by prescription. One of ordinary skill would also immediately appreciate that only a physician is capable of determining what amount would be therapeutically effective. Hardi Decl., ¶ 24.

Claim 7 additionally requires that the mammal that is the subject of administration be "in need of such treatment." One of ordinary skill reading this language would immediately recognize that the diagnosis of a physician is required, since only those individuals can capably determine that a subject 1) has gastrointestinal inflammatory disease (through diagnosis), and 2) requires treatment with the claimed formulation, in addition to determining the "therapeutically effective amount" as discussed above. Hardi Decl., ¶ 25.

One of ordinary skill in the art in the mid-1990's would have understood the term "administration" to also require the physician to prescribe the drug product to the subject being treated. In practice in the United States, such subjects are typically human patients. From the real world perspective of the person of ordinary skill in the art, prescription medications are federally regulated and can only be dispensed by entities licensed to do so, *e.g.*, pharmacies, managed healthcare organizations, etc., and on occasion the doctor himself. Hardi Decl., ¶ 26.

To complete the "administration" required by claims 6 and 7, the patient would need to orally ingest the prescribed drug product; "oral administration" is claimed. Hardi Decl., ¶ 27.

The '504 patent specification consistently supports Hanmi's constructions as to the meaning of "administration" in claims 6 and 7 and "mammal in need of treatment" in claim 7. Some relevant aspects of the '504 specification are shown below:

> Typical daily dose of the active compound will depend on various factors … such as … ***individual requirement of each patient,*** the ***route of administration*** and … (column 6, lines 21-25);
>
> It is desirable to obtain compounds with … which will give an improved ***therapeutic*** profile … (column 1, lines 50-53);

> The compounds of the invention may be used for inhibiting gastric acid secretion in mammals and man. In a more general sense, the compounds of the invention may be used for the ***treatment*** of gastric-acid related ***diseases*** and gastrointestinal inflammatory ***diseases*** in mammals and man … (column 2, lines 17-23);
>
> ...compounds may be used for ***treatment*** of other gastrointestinal disorders where gastric antisecretory is desirable, e.g., ***patients*** on NSAID therapy, in ***patients*** with gastrinomas, and in ***patients*** with acute upper gastrointestinal bleeding ... (column 2, lines 23-27);
>
> They may also be used in ***patients in intensive care*** situations and ***pre- and post-operatively*** … for ***treatment*** or ***prophylaxis*** of inflammatory conditions. Conditions that may be specifically mentioned for ***treatment*** are rheumatoid arthritis and gout … also useful in the ***treatment*** of psoriasis as well as ... Helicobacter infections (column 2, lines 17-37.)

'504 patent (emphases added). Based on these statements, one of ordinary skill would understand that the pharmaceutical formulations of the '504 patent are intended for 1) clinical therapeutic use, 2) "administration" occurs in the context of methods where the need for inhibiting gastric acid secretion has been recognized, and 3) therapeutically effective amounts will vary from subject to subject based on multiple factors ('504 patent at column 6, lines 21-25). Hardi Decl., ¶¶ 28-29.

Hanmi's construction tracks the context of the claims, the specification, file history and is supported by testimony from Dr. Hardi as to real world practice of the claimed methods. In contrast, AstraZeneca's construction for the "administration" terminology – "delivery by any suitable means, including but not limited to ingestion, which ***may*** include the prescription by a physician or other licensed health care professional, dispensing and ingestion" (D.I. 92-1, pages 4-5) – ignores the method of treatment context of claims 6 and 7, and is entirely at odds with the intrinsic evidence.[11] The fact that AstraZeneca argues for "delivery by any means" (such as an

[11] AstraZeneca's proposed construction for the express recitation in claim 7 of "mammal including man in need of such treatment": "a mammal including man who may obtain a benefit" (D.I. 92, Exhibit A, p. 4) essentially obliterates the presence of the terms "in need " and "treatment." The Federal Circuit has confirmed the construction of the phrase "a human in need thereof" as requiring that the "need" for therapy be recognized and appreciated and that the compound must be intentionally administered for

injection) when the claims plainly call for "oral administration" undermines AstraZeneca's credibility, and provides grounds by itself to reject its construction. Further, any construction in which the prescription, dispensing and ingestion of a therapeutically effective amount become optional is at odds with the intrinsic record and the real world practice of claims 6 and 7, and should be rejected.

B. The '192 Patent

1. "pharmaceutically acceptable salt"

Independent claims 1, 2 and 12 call for (-)-omeprazole or a "pharmaceutically acceptable salt" thereof. In the Joint Statement, Hanmi proposed two constructions:

> "Main" Construction (based on "incorporated" '512 specification): "Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt."
>
> "Alternative" Construction (based on '192 specification): "an acid or alkaline pharmaceutically acceptable nontoxic salt."

(D.I. 92-1, page 28.) Hanmi provided two constructions because there are two conflicting definitions if the incorporation by reference is upheld, as discussed below.

"Pharmaceutically acceptable salt" is not defined in the '192 patent claims. The '192 patent specification, however, purports to incorporate the parent '512 application's disclosure of the salt forms of (-)-omeprazole: "[t]he description of the salt forms of the single enantiomers of omeprazole and the process of making the same is herein incorporated by reference to copending Ser. No. 08/376,512." (Col. 1, lines 10-13). The main description of salt forms in the '192 patent is subject matter incorporated by reference from the parent '512 application (issued as the '504

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treatment of the recited condition. *See Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1332-33 (Fed. Cir. 2003). The combination of the phrase "treating or preventing" and the phrase "to a human in need thereof" compels a construction requiring the method to be practiced with the intentional purpose of achieving treatment of the condition recited in the claim. *Id.* at 1333; *see also citing Rapoport v. Dement*, 254 F.3d 1053, 1061 (Fed. Cir. 2001).

patent).[12] Because the '192 patent links the alleged clinical benefits set forth to the particular Na^+ and Mg^{2+} salts of the parent '512 application,[13] and discloses no other salts, the '192 claims can be no broader than the expressly described salt species in the '512 application (Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$) for the reasons set forth above in Section III-A-1. Hanmi's construction of "alkaline salts" as "Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$" should serve as at least a starting point in the construction of "pharmaceutically acceptable salt" in the '192 claims.

Despite the attempted incorporation by reference of non-specific parts of the parent '512 application (which is restricted to six particular salts), the '192 specification went on to include an ***explicit definition*** of "pharmaceutically acceptable salt:"

> The term "pharmaceutically acceptable salt" refers to both acid and alkaline pharmaceutically acceptable non-toxic salts.

('192 patent, col. 4, lines 13-16.) Thus, based on this explicit definition, under controlling precedent AstraZeneca's definition ("an acid or alkaline pharmaceutically acceptable non-toxic salt") must control. *Martek*, 579 F.3d at 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls."); *Phillips*, 415 F.3d at 1316.

Thus, while the '192 patent's intrinsic record is confusing, at the end of the day it appears that the Court would have no choice but to adopt the explicit and controlling definition of "an acid or alkaline pharmaceutically acceptable non-toxic salt." Although Hanmi is not aware of precedent on how to deal with two apparently conflicting definitions on the facts here, the Court could attempt to reconcile the apparent contradiction in the '504 patent's salt scope ("***The***

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[12] In this section, Hanmi assumes *arguendo* that at least some portions of the '512 application were properly incorporated by reference, although the Court should find that the attempted incorporation was legally deficient for the reasons presented in Section III-B-3 below.

[13] The experimental results of the '192 patent are based on clinical studies using the Na^+ and Mg^{2+} salts of (-)-omeprazole. *See* col. 4, line 60 to col. 7, line 16. No other alkaline salts are specifically disclosed in the '192 patent.

present invention refers to the new Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of the single enantiomers of omeprazole…" – *see* Section III-A-1 above) with the '192 patent's broader definition ("***an acid or alkaline pharmaceutically acceptable non-toxic salt***" – col. 4, lines 13-16), by melding the two. The '512 application disclosure that is incorporated by reference pertains solely to "alkaline salts" that are the subject of the '504 patent, as discussed above. The "pharmaceutically acceptable salts" as defined in the '192 patent include both acid and alkaline salts. Thus, the Court could fashion a combined construction where the acid component is broadly defined and the alkaline component is restricted per the '504 patent's definition. Faced with this dilemma, one of ordinary skill in the art would find this to be a rational solution. Atwood Decl. ¶¶ 21-25.

AstraZeneca's construction (D.I. 92-1, page 25) utterly ignores the plain definition of "pharmaceutically acceptable salt" that it drafted into the '192 patent. Nowhere in the Joint Claim Construction and Prehearing Statement (D.I. 91, 92) does AstraZeneca acknowledge that the '192 patentees acted as lexicographers in clearly defining this term as including both acid and alkaline components, and in so doing, firmly fixed the definition of "pharmaceutically acceptable salt." *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 789 (Fed. Cir. 2010) ("If the specification reveals a special definition for a claim term, the inventor's governs.") (*citing Phillips*, 415 F.3d at 1316); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("[T]he *claim term* will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed *claim term* in either the specification or prosecution history." (emphases added)).

AstraZeneca also retreats, without explanation, from the position advanced to the Court in *AZ v. DRL*, in which the Court stated:

> 13. "pharmaceutically acceptable salt

> This term appears in claims 1, 2, 7–9 and 12. ***Astra contends that this term should be construed to mean "both acid and alkaline nontoxic ionic compound."*** DRL contends that this term need not be construed and the ordinary meaning as understood by those of ordinary skill in the art should apply. However, if construction is required, DRL proposes that the phrase be construed as "a salt that is suitable for use in a pharmaceutical formulation."
>
> ***Once again, Astra's basis for its proposed construction of this term is nowhere addressed in Astra's claim construction papers.*** The Court, therefore, accepts DRL's argument that this term need not be construed.

2010 U.S. Dist. LEXIS 48844 at *62 (emphasis added). Although it is unclear why AstraZeneca could not point the Court to the controlling definition at column 4, lines 13-16, AstraZeneca clearly urged a position then that is contradictory to its position here – the "acid" part of the definition can simply be ignored. AstraZeneca's present inconsistent position should be rejected.

2. "consisting essentially of"

Each of independent claims 1, 2 and 12 expressly recites the language "consisting essentially of" (-)-omeprazole. Hanmi submits that this term should be construed in accordance with its customary legal meaning as follows:

> "necessarily including the listed ingredients[14] and open to unlisted ingredients that do not materially affect the basic and novel properties."

(D.I. 92-1, page 31.) The language "consisting essentially of" does not appear in the '192 patent's specification, or in the application as filed on April 11, 1997 which issued as the '192 patent (D.I. 111-9; D.I. 110). As the Court noted in the prior *AZ v. DRL* opinion, the language "consisting essentially of" was first introduced to the claim language during prosecution of the '192 patent. 2010 U.S. Dist. LEXIS 48844 at *30.

The intrinsic record – including the '192 patent's prosecution history (D.I. 110 to D.I 110-4) – makes clear that the language "consisting essentially of" was permitted to be added to

[14] "(-)-omeprazole" is the listed component of the claimed "proton pump inhibitor," which itself is nowhere mentioned much less defined in the '192 patent. The following Sections of this brief discuss the proper scope of "(-)-omeprazole," and the terms in combination.

the '192 claims during prosecution not because it has some special meaning in the context of optical purity of chemical compounds, but because it has a well-recognized *legal* meaning as a "transition" phrase. The Patent Office and courts have sanctioned its usage in claims even where, as here, there is no mention of the term in the specification. *PPG Indus. v. Guardian Indus. Corp*, 156 F.3d 1351, 1354 (Fed. Cir. 1998) ("By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention."); *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006) (*citing* MPEP § 2111.03 (Ex. 3)); *see also* John L. Landis, *Mechanics of Claim Drafting*, 2d Ed., (Practicing Law Institute, NY 1978) at 520.

Hanmi's proposed construction accords precisely with the well established legal meaning, and should be adopted here.

3. "(-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole"

Each of independent claims 1, 2 and 12 expressly recites "the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole." Hanmi submits that this term should be construed the same as in the '504 patent as:

"(-)-omeprazole" or the "(-)-enantiomer of omeprazole."

In *AZ v. DRL*, the Court noted that in the context of the parent '504 patent, a person of ordinary skill in the art would know that "[t]he '(-)' denotes that the compound has some level of optical purity" (*citing Abraxis* and *Ortho-McNeil,* 2010 U.S. Dist. LEXIS 48844 at *18-19; *see* Section III-A-2, *supra)*. Again, the Court's recognition of the well known '(-)' symbol in the compound's name as denoting one of the enantiomers, as opposed to the racemate or the other enantiomer, is consistent with Hanmi's proposed construction – (-)-omeprazole or the (-)-enantiomer of omeprazole.

The Court construed the phrase "consisting essentially of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" of the '192 patent independent claims 1, 2 and 12 as "a (-)-enantiomer that is essentially free of its (+) contaminant, which means at least 98% e.e.," basically agreeing with AstraZeneca's position (*see* 2010 U.S. Dist. LEXIS 48844 at *29-31).[15]

Hanmi respectfully submits that no basis exists for AstraZeneca to have previously urged, as its does now, that the claims should be limited to any specific lower limit of optical purity. The '192 patent's specification only states that the expression "single enantiomer refers to the fact that the (-)-enantiomer is substantially free from its (+) enantiomeric contaminant." *See* '192 patent at col. 1, lines 16-23 and 2010 U.S. Dist. LEXIS 48844 at *29. Even if the Court equates the claimed "(-)-enantiomer" with the unclaimed term "single enantiomer" and construes the independent claims as "substantially free of" (see footnote 15), there should be no inclusion of 98% e.e. as the floor for the following reasons.

First, there is no mention or discussion anywhere in the '192 patent's specification as printed of 98% e.e., or any other numerical lower limit. Atwood Decl. ¶¶ 40-45.

Second, the '192 patent's underlying application (Ser. No. 833,962) as filed on April 11, 1997 purports to be a continuation-in-part ("CIP") of "Ser. No. 376,512, Jan. 23, 1995, Pat. No. 5,714,504." *See* '192 patent, "Related U.S. Application Data; *see also* col. 1, lines 6-9 and 2010

[15] The '192 patent specification first discusses the term "(-)-enantiomer of [omeprazole]" at col. 1, lines 17-20, and goes on to define the term "single enantiomer" of (-)-omeprazole as "substantially free from its (+)-enantiomeric contaminant." Col. 1, lines 21-23. The claims of the '192 patent do not recite the term "single enantiomer." Nonetheless, Hanmi has no strong objection if the Court decides to equate the terms and adds "substantially free from its (+) enantiomeric contaminant" to Hanmi's proposed construction. Hanmi's objective in raising this issue is to eliminate the prior construction of the 98% e.e. limitation from the '192 claims, which AstraZeneca presses here without regard to the phrase "substantially free from its (+) enantiomeric contaminant" appearing at col. 1, lines 21-23. AstraZeneca's proposed construction (D.I. 92-1, page 24) differs from the Court's prior construction in this regard, which adopted its position.

U.S. Dist. LEXIS 48844 at *28, note 3.[16] By comparing the specifications of the '504 and '192 patents, it is readily apparent that there is little to no substantive subject matter in common. Nonetheless, the '192 patent purports to incorporate undefined, limited subject matter from the parent '512 application disclosure as follows: "The *description of the salt forms of the single enantiomers of omeprazole and the process of making the same* is herein incorporated by reference." '192 patent, col. 1, lines 10-13.

This vague reference to some aspects of the '512 parent application leaves one to guess exactly what portions are intended to be incorporated by reference, and what portions are not, a near impossible feat given the distinctiveness of the parent '512 application disclosure and the '192 specification. A mere reference to unidentified portions of a prior application does not serve to bring a disclosure within the requirements of 35 U.S.C. § 120 so as to give a later application the benefit of the filing date of an earlier application. To maintain continuity, each application must itself contain the necessary disclosure. *In re de Seversky*, 474 F.2d at 674; *Callaway Golf Co. v. Achushnet Co*., 576 F.3d 1331, 1346 (Fed. Cir. 2009); *Zenon Environmental, Inc. v. U.S. Filter Corp*., 506 F.3d 1370, 1378 (Fed. Cir. 2007) ("[t]o incorporate material by reference, the host document must identify ***with detailed particularity*** what specific material it incorporates and ***clearly indicate where*** that material is found in the various documents") (emphasis in original), citing *Advanced Display Systems v. Kent State University*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (same). Whether material has been incorporated by reference, and the extent of its incorporation, is a question of law, considered under a reasonable person of ordinary skill in the art standard. *Zenon,* 506 F.3d at 1378-79.

[16] A statement merely calling an application a "continuation-in-part," as here, does not in itself serve to incorporate by reference subject matter disclosed in a prior application. *In re de Seversky*, 474 F.2d 671, 674 (CCPA 1973). A statement that an application is a continuation-in-part of another application is in a broad sense a "reference" to the earlier application, but a mere reference to unidentified portions of a prior application, as here, is not an incorporation of anything therein into the later application for the purposes of the disclosure required by 35 U.S.C. § 112.

AstraZeneca's statement at col. 1, lines 10-13 of the '192 patent does not meet the *Zenon* Court's "detailed particularity" standard, *including where the "salt form" material is found in the reference document*. Was the Background section incorporated? What paragraphs of the Summary and Detailed Description sections? Only some of the Examples? No one knows. Because of the vague and ineffective attempt to incorporate non-specific portions of the prior '512 application into the later CIP application issued as the '192 patent, there is no legally recognized continuity of disclosure. *See Zenon Environmental, supra.* In such a case, use of the disclosure of the '512 parent's specification as support for claims terms in the later '192 patent must be barred.[17]

Nonetheless, even if, *arguendo*, some portion or the entirety of the parent '512 application was properly incorporated into the '192 specification – and Hanmi submits that it was not – the '192 claims still should not be limited to 98% e.e. It is significant that while all of the original claims of the parent '512 application call for particular *salts* of (-)-omeprazole, the '192 patent discloses and claims use of the *free base or neutral form* of (-)-omeprazole, *or* a pharmaceutically acceptable salt thereof. *See, e.g.,* '192 patent at col. 1, lines 16-22 and independent claims 1, 2 and 12. If the '192 claims are limited to 98% e.e., they would exclude the free base (-)-enantiomer reported in Example 12 of the '504 patent / '512 application, which states that the compound was obtained at 94% e.e. (col. 10, line 48 to col. 11, line 3) – the only example of making the free base enantiomer reported.[18] Atwood Decl. ¶ 46. A claim construction, however, should not exclude a preferred embodiment, let alone the sole

[17] In *AZ v. DRL,* the defendants did not appear to challenge the legality of the incorporation by reference, and in addressing this optical purity issue the Court appeared to assume that the entire *'504 patent* was incorporated into the '192 patent. 2010 U.S. Dist. LEXIS 48844 at *29-30.

[18] As noted above in connection with the '504 patent constructions in Section III-A-2, the '504 patent discloses an allegedly novel method of preparing both salt forms and neutral forms of the enantiomers of omeprazole. The free base or neutral forms of omeprazole are admitted to be old. *See* '504 patent at col. 1, lines 27-30 and col. 2, lines 11-15.

embodiment of a necessary component of the claim. *See Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("A construction which would result in excluding the preferred, and only, embodiment "is rarely, if ever, correct.").

Moreover, the Court in *AZ v. DRL* agreed with AstraZeneca's arguments that the phrase "consisting essentially of the (-)-enantiomer of (-)-omeprazole" in the independent claims of the '192 patent should be construed consistently with the term "optically pure" in claim 2 of the '504 patent. 2010 U.S. Dist. LEXIS 48844 at *28-30. Hanmi has no major qualms with this proposition, given the '504 patent's definition of "optically pure" as "essentially free of the (+)-enantiomer" (col. 3, lines 31-36) vs. the '192 patent *if* the term "(-)-enantiomer" (as opposed to "single enantiomer") is found to be defined as "substantially free from its (+)-enantiomeric contaminant" (col. 1, lines 16-23). Regardless, Hanmi pointed out in detail above in Section III-A-2 that limiting "optically pure" in claim 2 of the '504 patent to 98% e.e. is at odds with the intrinsic evidence – an express definition of "optically pure" not requiring a numerical limit, non-limiting "Examples," and AstraZeneca's election to discard the initial claims requiring "optically pure" compounds and replace them with optically impure claims except for claim 2. For the same reasons, to the extent the '504 patent and its prosecution history are considered despite the lack of a proper incorporation by reference, independent claims 1, 2 and 12 of the '192 patent should not be limited to 98% e.e. because the basis of that finding was the '504 disclosure. Atwood Decl. ¶ 47. Nothing in the prosecution history of the '192 patent requires a 98% e.e. limitation. Atwood Decl. ¶ 48.

4. "consisting essentially of (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole"

Each of independent claims 1, 2 and 12 expressly recites a proton pump inhibitor "consisting of essentially of (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-

pyridinyl)methyl]sulfinyl]-1H-benzimidazole." Putting the above constructions together, this phrase should be construed as:

> "(-)-omeprazole or the (-)-enantiomer of omeprazole, that may also contain substances that do not materially affect the claimed novel properties."

(D.I. 92-1, page 36.)

5. "administering to a mammal in need of treatment"

Each of independent claims 1 and 2 recites a method of treatment requiring administering to a mammal in need of treatment the claimed pharmaceutical formulation. Hanmi submits that this term should be construed as follows:

> "the prescription by a physician or other licensed healthcare professional, dispensing and delivery by any suitable means."

(D.I. 92-1, page 39.) Hanmi's position here tracks its position regarding the term "administration" in claims 6 and 7 of the '504 patent. *See* Section III-A-4, *supra.* Claim 1 of the '192 patent is representative:

> 1. A ***method for treatment of gastric acid related diseases by inhibition of gastric acid secretion*** comprising ***administering to a mammal in need of treatment a therapeutically effective amount*** of a proton pump inhibitor consisting essentially of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or a pharmaceutically acceptable salt thereof, so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases.

Given the precise context of claims 1 and 2, as reflected in bold above, in light of the manner in which such methods are actually carried out in day-to-day practice, Hanmi's interpretation tracks the views of a person of ordinary skill in the art in the mid-1990's. Hardi Decl. ¶¶ 30-33 and 35-38. The claims are to a method of treatment, only a physician can determine the "therapeutically effective amount," the drug product is only available by prescription, and therefore the prescription and dispensing aspects of Hanmi's construction are required. *Id.* Moreover, claims 1 and 2 require that the mammal is "in need of such treatment." One of ordinary skill reading this language would immediately recognize that the diagnosis of a physician is required, since

only those individuals can capably determine that a subject 1) has a "gastric acid related disease" (through diagnosis), and 2) requires treatment with the claimed formulation, in addition to determining the "therapeutically effective amount" as discussed above. Hardi Decl. ¶ 34.

To complete the "administering to a mammal in need of treatment" required by claims 1 and 2, the patient could be delivered the drug product by any suitable means. While claims 6 and 7 of the '504 patent specifically require oral ingestion, claims 1 and 2 of the '192 patent allow for oral ingestion, parenteral routes, etc. ('192 patent, column 4, lines 19-24). Hardi Decl. ¶ 36.

The '192 patent specification supports Hanmi's construction, and confirms that 1) the methods and formulations are intended for clinical therapeutic use, 2) "administering" occurs in the context of methods where the need for inhibiting gastric acid secretion, or treatment of a disease/condition has been recognized, and 3) therapeutically effective amounts will vary from patient to patient based on multiple factors. *See* '192 patent (D.I. 111-9) at col. 2, lines 13-63, col. 3, lines 37- 60; col. 4, lines 25-44 and col. 4, line 60 to col. 7, line 17; *see also* Hardi Decl. ¶¶ 37-38. AstraZeneca's construction in which the prescription, dispensing and delivery of the drug product become optional (D.I. 92-1, p. 23), does not comport with the intrinsic record and the real world practice of claims 1 and 2, and should be rejected. Likewise, AstraZeneca's proposed construction for "mammal in need of treatment" in the administering clause ("a mammal including man who may obtain a benefit" (*id.*)) ignores the terms "in need of" and "treatment." One of ordinary skill reading this language would immediately recognize that the diagnosis of a physician is required, for the reasons discussed in Section III-A-4 above.

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CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2011, I caused a copy of the foregoing HANMI'S OPENING *MARKMAN* SUBMISSION to be served upon the following counsel through the Court's ECF system and via mail:

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